EMORY HEALTHCARE

THE EMORY CLINIC, INC.

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July 10, 2000

Kathy Eberhart
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Suite 200 North, HFM 42
Rockville, MD 20852-1448

Dear Ms. Eberhart:

I understand that an open public meeting will be held on August 2, 2000 regarding the classification of human tissues as medical devices. Unfortunately, I will be unable to attend but I do want to provide documentation of my position on this matter.

In my practice as a neurological surgeon, a component of my work involves surgery of the spine. I have utilized bone allograft for selected cases throughout my practice and had experience with it during my training, a time that now encompasses nineteen years. During that time, I have not been aware of any untoward reactions related to the use of bone allograft. I believe that the current level of processing and regulation is adequate. I am familiar with the position paper on "the use of bone dowels from human tissue" by the American Association of Neurological Surgeons and Congress of Neurological Surgeons and I agree with the points made in that document. It is my opinion that additional regulation and restriction will offer no additional margin of safety to our patient population and that it will likely impede the availability of graft material as it is now used. I fully support the FDA's desire to maximize safety but believe that this specific plan should be abandoned.

Thank you very much for allowing me to have an opportunity to express my views. Please feel free to call me with any questions or concerns.

Sincerely,

Jeffrey J. Olson, M.D.
Associate Professor of Neurosurgery

JJO/lp

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